



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 6-882/S-033

Sanofi-Synthelabo, Inc.
Attention: Eileen De Micco, MA
Regulatory Specialist, Drug Regulatory Affairs
90 Park Avenue
New York, NY 10016

Dear Ms. De Micco:

Please refer to your supplemental new drug application dated August 21, 2002, received August 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for pHisoHex[®] (hexachlorophene detergent cleanser) Topical Emulsion.

We acknowledge receipt of your submission dated April 18, 2003.

Your submission of April 18, 2003 constituted a complete response to our December 20, 2002 action letter.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section of the labeling.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 18, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submissions should be designated "FPL for approved supplement NDA 6-882/S-033." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products (HFD-520)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth

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